UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ORTHO-MCNEIL : Civil Action No. 03-4678(SRC)

PHARMACEUTICAL INC., et al.,

Plaintiffs,

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v. :

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MEMORANDUM OPINION

BARR LABORATORIES, INC.,

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Defendant.

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HUGHES, U.S.M.J.

This matter having come before the Court upon Motion by Plaintiffs Ortho-McNeil Pharmaceutical, Inc. and Johnson & Johnson Pharmaceutical Research & Development, LLC ("Plaintiffs") to Preclude Trial Testimony of Dr. James A. Simon on "New Opinions Not Contained in His Expert Reports," [Docket Entry #51], returnable June 5, 2006. Defendant Barr Laboratories, Inc. ("Defendant") submitted opposition to the Motion claiming that a fair reading of Dr. Simon's report included the opinions expressed in his deposition testimony and, beyond that, there is no prejudice to Plaintiff if such testimony is allowed. The Court considered the submissions of the parties and conducted oral argument on June 5, 2006. For the reasons set forth below, Plaintiff's Motion to Preclude Trial Testimony of Dr. James A. Simon is denied.

I. BACKGROUND AND PROCEDURAL HISTORY

On October 1, 2003, Plaintiffs filed a Complaint against Defendant alleging willful infringement of United States Patent No. 6,214,815 ("the '815 patent") pursuant to 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355 [Docket Entry #1]. On October 14, 2003, Defendant filed its answer and counterclaim stating that "Claims 1, 2, 3, and 4 of the '815 patent are invalid for

failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code." [Docket Entry #3]. After numerous adjustments to the Scheduling Order, the Court set the deadline for initial expert reports for June 22, 2005 [Docket Entry #39]. Pursuant to this schedule, both parties served initial expert reports. Defendant included in its reports those of James A. Simon, M.D. and Sarah L. Berga, M.D., both of whom opined that the invention claimed in the '815 patent was invalid because it was anticipated or rendered obvious to the person of ordinary skill in the art by two prior art patents, United States Patent No. 4,616,006 ("the '006 patent") and United States Patent No. 4,628,051 ("the '051 patent"). These reports were nearly identical. On November 22, 2005, Defendant filed the Rebuttal Expert Report of James A. Simon, M.D., which asserted similar opinions as his previous report.

Depositions began shortly thereafter, and on December 20, 2005, Plaintiffs deposed Dr. Simon. During examination, Dr. Simon was unable to point to a reference in a direct paragraph or page in his report that would have suggested the '815 patent to a person of ordinary skill in the art, although he continually insisted that his report, in its entirety, supported his opinion. Simon Dep. 238:13-242:12, Dec. 20, 2005. Defendant continually objected to Plaintiffs' questioning on the record during the deposition. The next day, Defendant sent a letter to Plaintiff to follow up on the deposition and to inform Plaintiff that Dr. Simon's testimony about knowledge of a person of ordinary skill in the art would be included in the trial. *See* Letter from G. Pfadenhauer to J. Elikan, (Dec. 21, 2005), Exh. H. Plaintiff's response created the initial dispute over the proper interpretation of Dr. Simon's report. *See* Letter from J. Elikan to G.

¹ See Expert Report of James A. Simon, M.D. ("Simon Report") at ¶17-27, 30-37; Expert Report of Sarah L. Berga, M.D. ("Berga Report") at ¶23-33, 36-43.

Pfadenhauer (Dec. 21, 2005). The following day, Defendant's counsel questioned Dr. Simon, at which time he testified that a person of ordinary skill in the art would have known the facts stated in his report on the '006 and '051 patents and been motivated to create the claimed invention. Simon Dep. 462:19 - 466:21, Dec. 22, 2005.

One week before Dr. Berga's deposition, Defendant served a Supplemental Expert Report on her behalf, which contained the theory of motivation identical to that advanced by Dr. Simon during his deposition testimony. (Supplemental Expert Report of Sarah L. Berga, M.D. ¶ 2). Defendant submitted the report stating that it did so in order to prevent further confusion about the theory. Plaintiff immediately objected. In a hearing on January 24, 2006, this Court denied Plaintiff's request to preclude Dr. Berga from testifying to opinions not expressed in her initial expert report but permitted a supplemental rebuttal report. In the telephone hearing, the Court also said it was not inclined to allow Dr. Simon to submit a supplemental report because he had already been deposed. Defendant advised the Court that it did not intend to submit a similar report for Dr. Simon because it believed that his opinion was properly contained in his report.

As permitted by the Court, Plaintiffs filed the present Motion, [Docket Entry # 51], to Preclude Trial Testimony of Dr. James A. Simon on New Opinions Not Contained in His Expert Reports. Plaintiffs claim that (1) allowing such testimony would "irremediably prejudice" their case, (2) the decision to withhold the testimony was willful, and (3) Defendant would not be prejudiced by precluding the proposed testimony.

II. DISCUSSION

With this Motion, Plaintiffs seek to preclude Defendant from using the part of Dr. Simon's testimony which refers to his motivation theory. They claim that Dr. Simon's testimony violates Federal Rule of Civil Procedure 26(a)(2)(B) because his report does not

specifically state the opinion he put forth in the testimony. Plaintiffs further argue that even if the opinion could be inferred from the entirety of Dr. Simon's report, *In re Roufett*, 149 F.3d 1350 (Fed. Cir. 1998), requires heightened specificity when making claims of motivation. Thus, if the expert is required to state particular principles in his or her report that are known to a person of ordinary skill in the art, a theory of obviousness may be derived if that person of ordinary skill could have been motivated to create the patent in question from the known principles in the report.

The present case, however, can be distinguished from *Roufett* for two reasons. First, in *Roufett*, the plaintiffs were appealing a rejection of their patent application in the Federal Circuit. *Roufett*, 149 F.3d at 1356. The substantive issue of the matter required that the court use Federal Circuit law. The present Motion is procedural in nature and therefore, Third Circuit law controls. Second, because *Roufett* was an appeal, discovery was complete and redeposition of an expert would have been impractical at that stage of the proceeding. In the present Motion, discovery is ongoing and therefore, redeposing Dr. Simon would not delay or hinder the case. In addition, no trial date has been set.

Nonetheless, Plaintiffs contend that even under a Third Circuit analysis, *see Meyers v.*Pennypack Woods Home Ownership Association, 559 F.2d 894 (3d Cir. 1977), Plaintiffs would suffer prejudice if Dr. Simon's testimony was not excluded and that Defendant would not suffer prejudice because Dr. Berga would testify to the same theory as Dr. Simon. This court finds that Plaintiffs will not in fact be prejudiced by the inclusion of Dr. Simon's testimony and that if, conversely, his testimony was excluded, Defendant would be unfairly disadvantaged.

A. Full Disclosure - FED. R. CIV. P. 26(a)(2)(B)

Plaintiffs claim that there is good cause to preclude part of Dr. Simon's testimony because he included an opinion that he did not expressly include in his expert report. According

to FED. R. CIV. P. 26(a)(2)(B), the expert report must contain "a complete statement of all opinions to be expressed and the basis and reasons therefore." In this case, Plaintiffs argue that Dr. Simon did not include his theory of motivation within his report. Defendant, however, claims that Dr. Simon's entire report comprises his theory of motivation. The Court finds that a fair reading of Dr. Simon's report adequately discloses the motivation theory that he referenced in his deposition.

Dr. Simon states in his expert report that both the '006 patent and the '051 patent, when read through the eyes of the person of ordinary skill in the art, disclose the elements of the '815 patent. Simon Report at ¶ 27, 37, Exh. B. If this Court, however, finds that not every element of the '815 claim is present when the two previously mentioned patents are read by the person of ordinary skill in the art, Dr. Simon also asserts that the '815 patent is obvious to the person of ordinary skill in the art when considering the '006 and '051 patents as a whole. Although he does not specifically state this opinion in detail in his expert report, he does state that a person of ordinary skill in the art would have been "motivated" to make the claimed invention if they had combined their knowledge from reading the '006 and '051 patents. Simon Report at ¶ 28, 38, Exh. B. According to *Roufett*, if an expert claims that a combination of references made the patent obvious, the expert must show motivation. Rouffet, 149 F.3d at 1357. The Roufett court specifically stated that "the examiner must show reasons that the skilled artisan confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *Id.* Therefore, by stating that a person of ordinary skill in the art would be "motivated" to create the '815 patent, Dr. Simon is in essence stating that the patent would have been obvious to a person of ordinary skill in the art. Thus, while Dr. Simon may not have stated a particular theory of motivation in his report, he did adequately discuss motivation theories in general.

B. Excluding Witness Testimony - Pennypack Analysis

Moreover, Plaintiffs claim that their request to preclude Dr. Simon's opinion should be granted because permitting it would be inappropriate under a *Pennypack* analysis. *Pennypack*, 559 F.2d 894. Plaintiffs contend that not only will they be prejudiced by the inclusion of the testimony, but also that Defendant exhibited bad faith by attempting to question Dr. Simon about an opinion not specifically stated in the doctor's expert report. Defendant argues that any possible prejudice to Plaintiffs is curable because they have offered the opportunity to redepose Dr. Simon at Defendant's expense. Moreover, Defendant argues that if Dr. Simon's testimony is precluded, it will be unfairly prejudiced. Although Dr. Simon and Dr. Berga present the same theory, each one possesses a differing skill set and background, one academia, one clinical, and, Defendant argues, both are needed to enhance the credibility of Defendant's case.

In deciding whether to exclude witness testimony, a court must consider the following factors:

(1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court's order.

Pennypack, 559 F.2d at 905-06.

The four *Pennypack* factors can each be evaluated separately and each one will prove insufficient to support Plaintiffs' Motion. First, Dr. Simon's testimony is neither new nor revolutionary in this case because the same theory is found in both Dr. Berga's Supplemental Report and her testimony. Furthermore, Dr. Simon's theory, although not specifically stated in his report, could be inferred from the his deposition and various opinions he presented in the report regarding "motivation."

Second, Plaintiffs were given the opportunity to cure any prejudice against them by redeposing Dr. Simon. Moreover, Defendant had offered to pay for Dr. Simon to be redeposed, to relieve any further financial burden on Plaintiffs. During oral argument on June 5, 2006, Defense Counsel repeatedly offered to permit Plaintiff to redepose Dr. Simon at Defendant's expense, including reasonable attorneys fees, in order to clarify any possible misunderstanding about his theory and thus, promote fair examination and cross-examination at trial. Furthermore, Dr. Berga presented an identical theory in her Supplemental Report and deposition testimony to that of Dr. Simon. Thus, including Dr. Simon's testimony would not prejudice Plaintiffs because the same opinion would still be expressed through Dr. Berga's testimony.

Third, including Dr. Simon's testimony would not disrupt the scheduling of the trial because, as of yet, no trial date has been set. Plaintiffs argue that this duplication of theory would be unnecessary at trial and argue that the inclusion of Dr. Simon's testimony would be both burdensome and unnecessary. Defendant counters by stating that the qualifications of both doctors are significantly different (Dr. Simon's knowledge is derived from clinical practice whereas Dr. Berga's expertise is drawn from academia) and therefore, the testimony of each expert is needed at trial to buttress credibility of the particular theories. The Court, after examining the experts' backgrounds, find that while both experts may advance identical theories, they reach them through a meaningfully different skill set and background, and thus, cannot be considered cumulative. Moreover, the testimony of both experts may "assist the trier of fact," which, after all, is the purpose of expert testimony in the first place. *See* Fed. R. Evid. 702.

Fourth, Plaintiffs argue that Defense Counsel knew of Dr. Simon's "new" theory and purposefully acted in bad faith by not asking Dr. Simon to include his theory in his report.

Plaintiffs further allege that Defense Counsel acted in bad faith when he specifically introduced

the theory during his redirect of Dr. Simon. Although the Court empathizes with Plaintiffs'

Counsel's concern that they were "sand bagged," a trial attorney's worst nightmare, the Court

can find no evidence of willfulness or bad faith in the record before it.

III. CONCLUSION

Dr. Simon's report must be read fairly to have included a motivation theory and

therefore, Plaintiffs have failed to demonstrate good cause to preclude his deposition testimony

under FED. R. CIV. P. 26(a)(2). In addition, allowing the use of the testimony would not

prejudice Plaintiffs, because the theory is already being admitted into the trial through Dr.

Berga's report and testimony. Finally, precluding Dr. Simon's testimony would be prejudicial to

Defendant because although both experts propound the same theory, each has a meaningfully

different skill set and background. Conversely, any prejudice against Plaintiffs could be

remedied if the testimony were included because they are free to redepose Dr. Simon at

Defendant's expense.

For the reasons stated, Plaintiffs' Motion to Preclude Trial Testimony of Dr. James A.

Simon on "New Opinions Not Contained in His Expert Reports," is denied. An appropriate

Order accompanies this Memorandum Opinion.

/s/ John J. Hughes

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JOHN J. HUGHES

UNITED STATES MAGISTRATE JUDGE

DATED: June 29, 2006